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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/731,683

12/08/2003

Art Bertolero

021063-000510US

3268

20350 7590 05/28/2009
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EXAMINER

HOPKINS, CHRISTINE D

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

05/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/731,683	Applicant(s) BERTOLERO ET AL.	
	Examiner CHRISTINE D. HOPKINS	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-29,32-61,63 and 67-71 is/are pending in the application.
- 4a) Of the above claim(s) 24-29,35,36,46-52 and 57-61 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-23,32-34,37-40,63 and 69 is/are allowed.
- 6) ☒ Claim(s) 41-45,53-56,67,68,70 and 71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/18/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed 22 January 2009. Claims 20-29, 32-61, 63 and 67-71 are now pending, while claims 24-29, 35, 36, 46-52 and 57-61 remain withdrawn from consideration. The Examiner acknowledges the amendments to claims 20 and 41.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

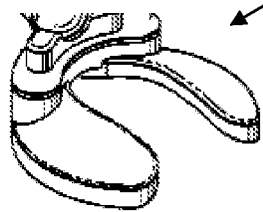
A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 41-43, 45, 53, 54, 56 and 70 are rejected under 35 U.S.C. 102(e) as being anticipated by Julian et al. (U.S. Pub. No. 2003/0158463). Regarding claims 41, 42, 45, 53, 56 and 70, Julian discloses a device comprising: a heart stabilizing member **1040** (or “heart positioning member” in accordance with claim 53) comprising a ball **1041, 1048**; an elongate coupling member **16** having a proximal end, a distal end, a flexible rigidifying portion **1072** comprising a plurality of pieces **36, 37** (beads) and a wire **20** that when tightened locks the pieces into place (Fig. 11E and [0115]), and means **1070** (“collet”) [0108] near the distal end for coupling with the heart stabilizing

member, and an actuation device (handle) near the proximal end that can tighten the coupling means to the ball of the heart stabilizing member and loosen the coupling means from the ball of the heart stabilizing member ([0099] and [0116]); and an elongate flexible arm **176** having a clamp **177**, wherein the elongate flexible arm is coupled with the elongate coupling member **16** via the clamp [0100] at a position proximal to the heart stabilizing member and distal to the actuation device ([0100], [0101] and Figs. 6A-6B).

Regarding claims 43 and 54, the heart stabilizing member **1040** comprises: at least one tissue contacting surface; and at least one suction aperture **1030** for applying suction force; and at least one coupling means **1020** for coupling with a source of suction (Fig. 7B).



4. Claims 67 and 71 are rejected under 35 U.S.C. 102(e) as being anticipated by Briscoe et al. (U.S. Patent No. 6,758,809). Briscoe et al. (hereinafter Briscoe) teaches a system comprising: a retractor device; a heart stabilizing device **21** comprising a tissue contacting surface, a suction aperture and a complementary coupling means; a first coupling device comprising an elongate shaft **20** having a proximal end, a distal end and at least one flexible rigidifying portion comprising a plurality of “beads” and a wire **40** that when tightened locks the pieces of the rigidifying portion into place, a distal coupling means at or near the distal end, and an actuation device **23** at or near the proximal end that can tighten and loosen the distal coupling means, and a first flexible arm **20a** coupled with the first coupling device **20** via a first clamp (turret assembly),

wherein the first flexible arm can be rigidified by applying suction (Fig. 1A and col. 3, lines 29-44 - col. 4, lines 1-16 and col. 5, lines 13-46).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 44 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Julian et al. (U.S. Pub. No. 2003/0158463) in view of Houser et al. (U.S. Pub. No. 2003/0060685). Julian discloses the invention as claimed, see rejection supra; however Julian does not teach inflating a tissue contacting surface of the heart stabilizing or positioning member. Houser et al. (hereinafter Houser) teach a surgical instrument for contacting and stabilizing tissue of the heart. Regarding claims 44 and 55, Houser teaches a heart stabilizing or positioning member **100** having a tissue contacting surface **120**. The contacting section may be configured to provide a variety of atraumatic surfaces, as well as ways to prevent slippage and invoke immobilization of the heart. Houser teaches a member or "port" to supply vacuum, a stream of fluid, or an inflatable medium to abut the contacting section against the surface of the heart [0113]. Furthermore, Houser teaches the introduction of an inflation medium through the same conduit for supplying vacuum, which immobilizes the heart (as in the instant

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application). It is also noted that Julian teaches a conduit for supplying fluid or gas to a worksite [0091]. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have provided an inflation medium as suggested by Houser, to a heart stabilizing or positioning member as taught by Julian, such that minimal damage is imparted to the sensitive cardiac tissue.

7. Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Briscoe et al. (U.S. Patent No. 6,758,809) in view of Spence et al. (U.S. Patent No. 6,390,976). Briscoe discloses the invention as claimed, see rejection supra; however Briscoe does not disclose the use of a system comprising two sets of coupling devices (arms) and heart stabilizing devices. Spence discloses an additional surgery immobilizer ("heart positioning device") to further support the heart during surgery and isolate a particular area that is to be targeted during surgery (col. 6, lines 47-67 - col. 7, lines 1-12). This device similarly employs a suction cup with apertures in order to immobilize the area (Figs. 12 and 15). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to have incorporated two heart positioning devices as disclosed by Briscoe, to a heart stabilizing system as taught by Spence, in order to more effectively target and manipulate a particular area of the heart receiving surgical treatment.

Allowable Subject Matter

8. Claims 20-23, 32-34, 37-40, 63 and 69 are allowable over the prior art of record. The following is a statement of reasons for the indication of allowable subject matter:

regarding claims 20-23, 32-34, 37-40, 63 and 69, the prior art of record does not teach or fairly suggest a system for enhancing heart surgery as claimed by Applicant, wherein the device further comprises a first flexible arm for coupling the first coupling device with at least one stable object, wherein the first flexible arm comprises a distal clamp configured to clamp the first coupling device, and a proximal clamp configured to clamp the at least one stable object.

Response to Arguments

9. Applicant's arguments filed 22 January 2009 with respect to the rejection of claims 41-43, 45, 53, 54, 56 and 70 under 35 U.S.C. 102(b) citing Fox et al. ('730) have been fully considered but are moot in view of the new grounds of rejection under 35 U.S.C. 102(e) citing Julian et al. ('463).

10. Applicant's arguments filed 22 January 2009 with respect to the rejection of claims 67 and 71 under 35 U.S.C. 102(e) citing Briscoe ('809) have been fully considered and are not persuasive. Applicant contends that Briscoe does not disclose a retractor device. However, this argument is not persuasive. Applicant's attention is drawn specifically to col. 3, lines 39-42 for the teaching of a retractor device. Applicant further contends that there is no showing in Briscoe that arm **20a** can be rigidified by applying suction. However, this argument is not persuasive. While the suction means (vacuum connection **25**) may be located exterior to the elongate shaft, the flexible, interlocking ("ball and socket links") construction (col. 3, lines 42-44) of the elongate

shaft make it capable of being rigidified by suction. In view of the foregoing, the rejection of claims 67 and 71 under 35 U.S.C. 102(e) citing Briscoe ('809) has been maintained.

11. Applicant's arguments filed 22 January 2009 with respect to the rejection of claims 44 and 55 under 35 U.S.C. 103(a) citing Fox et al. ('730) in view of Houser et al. (U.S. Pub. No. 2003/0060685) have been fully considered but are moot in view of the new grounds of rejection presented above citing Julian et al. ('463) in view of Houser et al. (U.S. Pub. No. 2003/0060685).

12. Applicant's arguments filed 22 January 2009 with respect to the rejection of claim 68 under 35 U.S.C. 103(a) citing Briscoe et al. (U.S. Patent No. 6,758,809) in view of Spence et al. (U.S. Patent No. 6,390,976) have been fully considered and are not persuasive. Applicants' arguments are contingent upon those presented with regards to claim 67, which is addressed above. In view of the foregoing, the rejection of claim 68 under 35 U.S.C. 103(a) citing Briscoe et al. (U.S. Patent No. 6,758,809) in view of Spence et al. (U.S. Patent No. 6,390,976) has been maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE D. HOPKINS whose telephone number is (571)272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. D. H./
Christine D Hopkins
Examiner
Art Unit 3735

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735